PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 121772	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. **PCT**/AU2005/000067	International filing date *(day/month/year)* 21 January 2005	Priority date *(day/month/year)* 22 January 2004
International Patent Classification (IPC) or national classification and IPC Int. Cl. ***A61F 2/24*** (2006.01)		
Applicant AUSTRALIAN SURGICAL DESIGN AND MANUFACTURE PTY LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of **6** sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[X]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
31 October 2005	15 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer D. Melhuish **DAVID MELHUISH** Telephone No. (02) 6283 2426

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International application No.
PCT/AU2005/000067

Box No. I Basis of the report

1. With regard to the **language,** this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1 – 9, 11 – 13** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* **10** received by this Authority on **31 October 2005** with the letter of **31 October 2005**

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* received by this Authority on with the letter of
pages* **14 – 18** received by this Authority on **9 February 2006** with the letter of **9 February 2006**

[X] the drawings:

pages **1/5 – 5/5** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: **23, 24, 25 (in part), 26 (in part)**

because:

☐ the said international application, or the said claims Nos.
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*

☒ no international search report has been established for said claim Nos. **23, 24, 25 (in part), 26 (in part)**

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ neither restricted the claims nor paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

   The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

   1. Claims 1 to 22, 25 (in part), 26 (in part) directed to a heart valve comprising an annular body portion and a support ring, wherein the annular body portion is rotatable relative to the support ring. It is considered that the relative rotation between the body portion and the support ring comprises a first "special technical feature".

   2. Claims 23, 24, 25 (in part), 26 (in part) directed to a heart valve comprising an annular body portion and a support ring, wherein the body portion is mounted to the support ring so as to be moveable from a sealed position to a position defining a second fluid pathway between the body portion and the support ring. It is considered that the second fluid pathway comprises a second special technical feature.

   Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. **1 – 22, 25 (in part), 26 (in part)**

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1 – 22, 25, 26**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1 – 22, 25, 26**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1 – 22, 25, 26**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

Claims 1 – 22, 25, 26:

Claims 1 to 22, 25 and 26 meet the requirements of PCT Articles 33(2) – (4). None of the prior art documents, or obvious combination thereof, disclose a valve assembly comprising an annular body and a support ring, wherein the annular body and the support ring are moveable relative to each other to open up a second fluid pathway through the valve assembly. The claims are therefore novel and inventive. The claims also have industrial applicability.

body 30 is shown in Figures 2(c) and 2(d) wherein the moveable leaflets 32 are again shown in the first or closed position 34 and in the second or open position 35. Figures 2(e) and 2(f) provide a plan view of the valve body 30 with again the moveable leaflets 32 being in the first or closed position 34 and in the second or open position 35.

An example of the operation of the valve body 30 is depicted in Figures 3(a) and 3(b). When in the second or open position 35, as shown in Figure 3(b), the moveable leaflets 32 provide a first fluid pathway represented by arrow 33 through the valve assembly 10. When the leaflets 32 are in the first or closed position 34, the moveable leaflets 32 work together to occlude the first fluid pathway 33 as shown in Figure 3(a), occluding blood flow through the valve in the opposite direction as shown by the arrow denoting the direction of flow through the first fluid pathway 33.

In this example, the moveable leaflets 32 are arranged such that upon subject to the first pressure differential across the valve body, blood flow through the first fluid pathway 33 causes the leaflets and the annular body portion 31 to rotate with respect to the support ring 20. The leaflets 32 are angled relative to the direction of blood flow through the first fluid pathway 33 and are caused to rotate which in turn rotates the annular body portion 31 with respect to the support ring 20 as blood flows past the leaflets 32 through the first fluid pathway 33. As depicted in Figures 2(a) and 2(b), the leaflets are substantially cup-shaped with an outer convex surface 51 and an inner concave surface 52.

The plurality of moveable leaflets 32 are configured such that they move toward the second or open position 35 progressively upon progressive change of pressure from the first pressure differential to the second pressure differential. As the blood flow reduces at the end of systole the momentum of the rotating valve would then tend to start closing down as it drove against the relatively slower moving blood. As the blood flow ceases, momentarily before the pressure is exerted backwards on the valve, the moveable leaflets 32 are relatively close to the first or closed position 34 to occlude the first fluid pathway 33. This compares to all other valves where this is the moment at which shutting commences, so that the fall back pressure and leak is therefore higher and noisier as the valve snaps shut. This "snapping shut" is the cause of normal heart sounds in well functioning valves.

CLAIMS:

1. A valve assembly comprising:

a support ring having an outer surface and an inner surface;

a valve body comprising an annular body portion supporting a plurality of moveable leaflets that are moveable relative to the annular body portion and to each other between a first closed position and at least one second open position defining a first fluid pathway through the assembly when subject to a first pressure differential across the body;

wherein the annular body portion is mountable to the inner surface of the support ring and is relatively rotatable thereto;

and further wherein the annular body portion is moveable relative to the support ring from a sealed position to at least one unsealed position, the annular body portion and the support ring, in the unsealed position, together defining a second fluid pathway through the assembly.

2. A valve assembly for implantation in the cardio-vascular system of a human or animal subject, the valve assembly comprising:

a support ring having an outer surface and an inner surface, the outer surface being engageable with the wall of a vessel of the human or animal subject; and

a valve body comprising an annular body portion supporting a plurality of moveable leaflets that are moveable relative to the annular body portion and to each other between a first closed position and at least one second open position defining a first fluid pathway through the assembly when subject to a first pressure differential across the valve body;

wherein the annular body portion is mountable to the inner surface of the support ring and is relatively rotatable thereto;

and further wherein the annular body portion is moveable relative to the support ring from a sealed position to at least one unsealed position, the annular body portion and the support ring, in the unsealed position, together defining a second fluid pathway through the assembly.

3. The valve assembly of claim 1 or claim 2 wherein when the valve assembly is subjected to a second pressure differential, the plurality of leaflets move to their first closed position.

4. The valve assembly of any one of the preceding claims wherein the first pressure differential comprises a region of higher pressure upstream of the valve assembly relative to a lower pressure downstream of the valve.

5. The valve assembly of any one of the preceding claims wherein the second pressure differential comprises a region of lower pressure upstream of the valve assembly relative to a region of higher pressure downstream of the valve assembly.

6. The valve assembly of claim 1 or claim 2 wherein the annular body portion moves to its at least one unsealed position when the assembly is subjected to the first pressure differential.

7. The valve assembly of claim 6 wherein the annular body portion is not in engagement with the support ring in its unsealed position.

8. The valve assembly of any one of the preceding claims wherein the leaflets extend inwardly from and at an angle to the annular body portion when in their closed position.

9. The valve assembly of claim 8 wherein the leaflets together form a convex body that extends in a first direction away from the annular body portion when the leaflets are in their first closed position.

10. The valve assembly of any one of the preceding claims wherein at least one leaflet overlaps at least a portion of an adjacent leaflet when in their first closed position.

11. The valve assembly of any one of the preceding claims wherein the leaflets move progressively upon progressive change of pressure between the first pressure differential and the second pressure differential.

12. The valve assembly of any one of the preceding claims wherein at least one of the leaflets has a surface coating or the surface has been treated to reduce turbulence of fluid flowing past and/or over the leaflets.

13. The valve assembly of any one of the preceding claims wherein the moveable leaflets are hingedly connected to the annular body portion of the valve body.

14. The valve assembly of any one of claims 1 to 12 wherein the moveable leaflets are fixedly connected to the annular body portion of the valve body.

15. The valve assembly of any one of the preceding claims wherein the leaflets are made from a biological material selected from the group comprising autologous graft tissue, allograft tissue and xenograft tissue.

16. The valve assembly of any one of claims 1 to 14 wherein the moveable leaflets are made from an artificial material selected from the group comprising polymers, composites, metals and metal alloys including Nitinol™.

17. The valve assembly of any one of the preceding claims wherein the support ring is made from a ceramic, a metal or a metal alloy material including a Cobalt-Chromium alloy.

18. The valve assembly of any one of the preceding claims wherein the annular body portion is made from a ceramic, a metal or a metal alloy material including a Cobalt-Chromium alloy.

19. The valve assembly of any one of the preceding claims wherein the annular body portion includes a turbine member to optimise rotation of the annular body portion.

20. The valve assembly of any one of the preceding claims wherein the annular body portion and the support ring are provided as a single unit for implant into a system or subject.

21. The valve assembly of any one of claims 1 to 19 wherein the annular body portion and the support ring are provided as separate components.

22. The valve assembly of any one of the preceding claims when used to replace any valve of the cardiovascular system including the aortic valve, the pulmonary valve, the tricuspid valve and the mitral valve.

23. A valve for implantation in the cardio-vascular system of a human or animal subject, the assembly comprising:

a support ring having an outer surface and an inner surface, the outer surface being engageable with the wall of a vessel of the human or animal subject; and

a valve body comprising an annular body portion supporting a plurality of leaflets that are moveable relative to the annular body portion and to each other, the leaflets being moveable between a first closed position and at least one second opened position defining a first fluid flow pathway through the assembly when subject to a first pressure differential across the body;

wherein the annular body portion is mountable to the inner surface of the support ring and is relatively moveable from a sealed position to at least one unsealed position defining a second fluid pathway through the assembly when the assembly is subject to the first pressure differential.

24. The valve of claim 23 wherein the annular body portion is also relatively rotatable with respect to the support ring.

25. A method of implanting a valve assembly within the cardio-vascular system of a patient; the method comprising delivering the valve assembly of any one of claims 1 to 22 or the valve of claim 23 or claim 24 within a vascular vessel of the patient.

26. The method of claim 25 wherein the support ring is delivered separately to the valve body and as a first step.